

TRANSMITTAL OF APPEAL BRIEFDocket No.
FLH-10902/29

In re Application of: Mark Falahee

Application No.
10/689,124-Conf. #2910Filing Date
October 20, 2003Examiner
D. YabutGroup Art Unit
3734

Invention: RADIOPAQUE MARKING PEN

TO THE COMMISSIONER OF PATENTS:Transmitted herewith is the Appeal Brief in this application, with respect to the Notice of Appeal
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Dated: April 29, 2008

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS AND INTERFERENCES**

In re Patent Application of: Mark Falahee

Application No.: 10/689,124

Confirmation No.: 2910

Filed: October 20, 2003

Art Unit: 3734

For: RADIOPAQUE MARKING PEN

Examiner: D. Yabut

APPELLANT'S APPEAL BRIEF UNDER 37 CFR §41.37

Mail Stop APPEAL BRIEF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I. Real Party in Interest

The real party in interest in this case is Medical Designs, LLC, by assignment.

II. Related Appeals and Interferences

There are no appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. Status of Claims

The present application was filed with 16 claims. Claims 1-16 are pending, rejected and under appeal. Claim 1 is the sole independent claim.

IV. Status of Amendments

An after-final amendment is being submitted herewith correcting a typographical error in claim 13, which was pointed out by the Examiner in the final Office Action. An amendment to claim 2 has also been made to overcome the 35 U.S.C. §112, second paragraph rejection. Neither

of these amendments have been reflected in the Appendix A, Claims on Appeal section of this Brief. Claim 15 has been canceled as it is a duplicate of claim 14.

V. Summary of Claimed Subject Matter

Independent claim 1 is directed to a marker particularly valuable to performing invasive surgical procedures. The marker comprises a housing in the form of a marking pen, and a reservoir in the housing that is filled with a substance which, when dispensed through the marking pen, is radiopaque. (Specification, page 2, lines 2-5; 20-28).

Claim 13 resides in a method of preparing for a surgical procedure. The method comprises the steps of providing the marking pen of claim¹ 1; indicating an operative site using the marking pen; and subjecting the site to x-ray exposure for the purpose of comparing the indication to one or more internal structures associated with the procedure. (Specification, page 3, lines 1-85)

Claim 9 adds to claim 1 the substance is primarily a powder. (Specification, page 3, lines 1-85)

Claim 14 adds to claim 13 the step of indicating an operative site using the marker includes marking a surgical film. (Specification, page 2, lines 26-28)

Claim 16 adds to claim 13 the step of erasing the indication if not optimized for the procedure. (Specification, page 3, lines 6-8)

VI. Grounds of Rejection To Be Reviewed On Appeal

A. The rejection of claims 1-8 and 10-12 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,689,103 to Palasis, wherein claims 2-8 and 10-12 stand/fall with claim 1.

B. The rejection of claim 13 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,689,103 to Palasis.

C. The rejection of claims 9 and 14 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,689,103 to Palasis in view of U.S. Patent No. 6,198,807 to DeSena.

D. The rejection of claim 16.

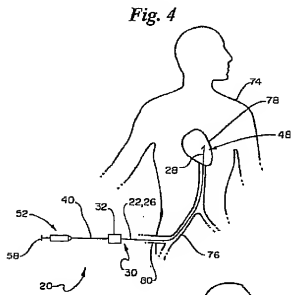
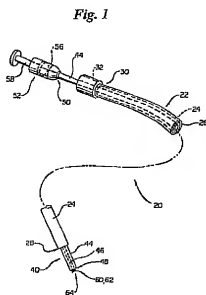
¹ In order to correct this typographical error, Appellant has replaced "Figure" with "claim" in the Amendment and Response to Final Office Action filed herewith.

VII. Arguments

A. Claims 1-8 and 10-12, wherein claims 2-8 and 10-12 stand/fall with claim 1.

Appellant's invention resides in a marker particularly valuable to performing invasive surgical procedures. According to claim 1, the article comprises a housing *in the form of a marking pen*, and a reservoir in the housing that is filled with a substance which, when dispensed through the marking pen, is radiopaque. This allows the surgeon to mark the skin or surgical film with a substance that can be easily visualized via x-ray, under c-arm, for example.

Claims 1-8 and 10-13 stand rejected under 35 USC §102(e) over Palasis ('103). Palasis is directed to a fluid delivery system for delivering and injecting fluid into heart tissue, or other organ tissues ('103 Patent, Abstract). The fluid delivery system includes an injection catheter disposed in an elongate sheath. A nozzle, including an injection array, is disposed adjacent the distal end of the injection catheter. Appellant has reproduced Figures 1 and 4 of Palasis, below:



The Examiner argues that "Palasis discloses a marker comprising a housing 22 in the form of a marking pen..." (Final OA, p. 3, emphasis by Examiner). This interpretation is unreasonable. "Housing" 22 of Palasis is a flexible sheath intended for introduction into a patient's heart, as shown in Figure 4.

Claim interpretation must be consistent with the specification. *In re Hyatt*, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000). Indeed, the broadest reasonable interpretation must also be consistent with the interpretation *that those skilled in the art would reach*. *In re Cortright*, 165 F.3d 1353, 1359, 49 USPQ2d 1464, 1468 (Fed. Cir. 1999).

"[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, *i.e.*, as of the effective filing date of the patent application." *Phillips v. AWH Corp.*, 415 F.3d 1301 (Fed. Cir. 2005), 75 USPQ2d 1321 (Fed. Cir. 2005) (*en banc*); *Sunrace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1298, 1302, 67 USPQ2d 1438, 1441 (Fed. Cir. 2003); *Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1298 67 USPQ2d 1132, 1136 (Fed. Cir. 2003)("In the absence of an express intent to impart a novel meaning to the claim terms, the words are presumed to take on the ordinary and customary meanings attributed to them by those of ordinary skill in the art."). It is the use of the words in the context of the written description and customarily by those skilled in the relevant art that accurately reflects both the "ordinary" and the "customary" meaning of the terms in the claims. *Ferguson Beauregard/Logic Controls v. Mega Systems*, 350 F.3d 1327, 1338, 69 USPQ2d 1001, 1009 (Fed. Cir. 2003).

The written description must be examined in every case, because it is relevant not only to aid in the claim construction analysis, but also to determine if the presumption of ordinary and customary meaning is rebutted. *See Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250, 48 USPQ2d 1117, 1122 (Fed. Cir. 1988). The presumption will be overcome where the patentee, acting as his or her own lexicographer, has clearly set forth a definition of the term different from its ordinary and customary meaning. *See In re Paulsen*, 30 F.3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994); *Intellicall, Inc. v. Phonometrics, Inc.*, 952 F.2d 1384, 1387-88, 21 USPQ2d 1383, 1386 (Fed. Cir. 1992). The presumption also will be rebutted if the inventor has disavowed or disclaimed scope of coverage, by using words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope. *See Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1324, 63 USPQ2d 1374, 1380 (Fed. Cir. 2002).

In this instance, Appellant has not departed from the ordinary and customary meaning of marking pen. To any person of skill, in practically any art, "marking pen" means a pen-shaped implement used to mark things. Nobody (other than the Examiner in this case) would stretch the

definition of "marking pen" to include a flexible catheter adapted for introduction into a human heart.

Appellant's claim 1 further includes the limitation of "a reservoir *in the housing*..." Palasis does not have this. According to the '103 patent, "[a] fluid source 52 is releasably connected to the proximal end 50 of injection catheter 40. Fluid source 52 in fluid communication with lumen 46 of elongate tubular member 44. Fluid source 52 is capable of injecting fluid into lumen 46 of elongate tubular member 44." See '103, 5:20-25 and Figures, above.

Anticipation may be established only when a single prior art reference discloses, expressly or under principles of inherency, each and every element of a claimed invention. *RCA Corp. v. Applied Digital Data Systems*, 730 F.2d 1440, 1444, 221 USPQ 385, 388 (Fed. Cir. 1984). Moreover, anticipation requires the presence of all elements of a claimed invention as arranged in the claim, such that a disclosure "that 'almost' meets that standard does not 'anticipate'." *Connell v. Sears, Roebuck Co.*, 722 F.2d 1542, 1548, 220 USPQ 193, 198 (Fed. Cir. 1983).

Since Palasis neither teaches nor suggests "a housing in the form of a marking pen or a reservoir in the housing, *prima facie* anticipation has not been established. Indeed, Palasis is not even analogous art. "In order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicants endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned." *In re Oetiker*, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). See also *In re Deminski*, 796 F.2d 436, 230 USPQ 313 (Fed. Cir. 1986); *In re Clay*, 966 F.2d 656, 659, 23 USPQ2d 1058, 1060-61 (Fed. Cir. 1992) ("A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem."); and *Wang Laboratories Inc. v. Toshiba Corp.*, 993 F.2d 858, 26 USPQ2d 1767 (Fed. Cir. 1993).

In this case, catheters have nothing to do with marking pens. Although Appellant's invention uses radio-opaque ink and the system of Palasis uses a contrast solution, the fluid of Palasis would dribble all over a patient's body if the catheter were operated against the skin, thereby precluding use as an ink for marking. Thus, the Examiner's argument that "the device of [Palasis] would be capable of marking skin or surgical film" (Final OA, p. 5) is wrong. According to Palasis

a limitation to previous methods of delivering therapeutic agents to the heart “is that the injected fluid tends to leak and/or disperse from the site of the injection after the needle is disengaged from the heart. In fact, fluid may continue to leak over several seconds. In the case of dynamic organs such as the heart, there may be more pronounced leakage with each muscle contraction.” (’103 Patent, 1:34-41)

B. Claim13

Claim 13 resides in a method of preparing for a surgical procedure, comprising the steps of: providing the marking pen of claim² 1; indicating an operative site using the marking pen; and subjecting the site to x-ray exposure for the purpose of comparing the indication to one or more internal structures associated with the procedure.

This claim also stands rejected under 35 U.S.C. §102(e) over Palasis. The Examiner argues that these steps are taught by Palasis in Figure 1; col. 7, line 48 to col. 8, line 15; col. 9, lines 1-4; and col. 11, lines 12-23). This is not true. Figure 1 has already been discussed and it teaches nothing of the kind. Col. 7, line 48 to col. 8, line 15 of Palasis simply discusses how radiopaque contrast solution may be dispensed from distal end 28 of sheath 22 to enhance fluoroscopic visualization. This has nothing to do with indicating an operative site using a marking pen or comparing the indication to one or more internal structures.

Col. 9, lines 1-4 of Palasis reads as follows:

“Radiopaque solution may be used to mark an area. For example, when performing PMR, it may be desirable to mark the locations of wound formation.”

A PMR is a “percutaneous myocardial revascularization” procedure, which is aimed at assuring that the heart is properly oxygenated. In a healthy heart, blood perfusion is accomplished with a system of blood vessels and capillaries. However, it is common for the blood vessels to become occluded (blocked) or stenotic (narrowed). A PMR procedure generally involves the creation of holes, craters or channels directly into the myocardium of the heart. In a typical PMR procedure, these holes are created using radio frequency energy delivered by a catheter having one or more electrodes near its distal end. After the wound has been created, therapeutic agents are

² In order to correct this typographical error, Appellant has replaced “Figure” with “claim” in the Amendment and Response to Final Office Action filed herewith.

sometimes ejected into the heart chamber from the distal end of a catheter. Thus, the passage cited by the Examiner also has nothing to do with indicating an operative site using a marking pen or comparing the indication to one or more internal structures.

Finally, col. 11, lines 12-23 of Palasis describes how “the fluid injected into the heart tissue may also include a radiopaque material. Injecting a radiopaque material into the wound effectively marks the locations which have been treated. This will aid the physician in procedures which are being performed percutaneously using fluoroscopic equipment.” No marking pen is disclosed, and no comparisons are made. Accordingly, *prima facie* anticipation has not been established.

C. Claims 9 and 14.

With regard to claims 9 and 14, the Examiner argues that it would be obvious to provide Palasis with a powered substance and mark a surgical film “since it was known in the art that powder is minimally invasive, and that marked surgical film is minimally invasive and easily removed...” Appellant does not quite understand the grounds for rejection in that “minimally invasive” generally refers to a procedure and not substances. In any case, Palasis is clearly directed to invasive procedures unrelated to marking skin, films, erasure, and so forth.

In the final Office Action, the Examiner clarifies that powder is “minimally invasive [in that it] does not injure or necessarily penetrate tissue.” This runs counter to the accepted definition of “minimally invasive.” Minimally invasive surgical procedures avoid open invasive surgery in favor of closed or local surgery with less trauma. These procedures involve use of laparoscopic devices and remote-control manipulation of instruments with indirect observation of the surgical field through an endoscope or similar device, and are carried out through the skin or through a body cavity or anatomical opening. This has nothing whatsoever to do with “powder.”

D. The Rejection of Claim 16.

Although the Examiner “rejects” this claim on the cover sheet of the Office Action, no art is applied. Presumably, like the other claims of this application, it is allowable.

Conclusion

In conclusion, for the arguments of record and the reasons set forth above, all pending claims of the subject application continue to be in condition for allowance and Appellant seeks the Board's concurrence at this time.

Dated: April 29, 2008

Respectfully submitted,

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APPENDIX A
CLAIMS ON APPEAL

1. A marker particularly valuable to performing invasive surgical procedures, comprising:

a housing in the form of a marking pen; and

a reservoir in the housing that is filled with a substance which, when dispensed through the marking pen, is radiopaque.

2. The marking pen of claim 1, wherein the ink is also visible to the human eye.

3. The marker of claim 1, wherein the substance is capable of marking human skin.

4. The marker of claim 1, wherein the substance is capable of marking a commercially available surgical film.

5. The marker of claim 1, wherein the substance includes a metal.

6. The marker of claim 1, wherein the substance includes a heavy metal.

7. The marker of claim 1, wherein the substance includes barium.

8. The marker of claim 1, wherein the substance is primarily a liquid.

9. The marker of claim 1, wherein the substance is primarily a powder.

10. The marking pen of claim 1, wherein the substance is erasable.

11. The marker of claim 1, wherein the substance is biocompatible.

12. The marker of claim 1, wherein the substance is non-toxic.
13. A method of preparing for a surgical procedure, comprising the steps of:
providing the marking pen of Figure 1;
indicating an operative site using the marking pen; and
subjecting the site to x-ray exposure for the purpose of comparing the indication to one or more internal structures associated with the procedure.
14. The method of claim 13, wherein the step of indicating an operative site using the marker includes marking a surgical film.
16. The method of claim 13, further including the step of erasing the indication if not optimized for the procedure.

APPENDIX B

EVIDENCE

None.

APPENDIX C

RELATED PROCEEDINGS

None.